

REPLY

Serial No. 08/480,472
Atty. Docket No. GP034-03.DV1

view of Suzuki *et al.* (*J. Bact.* (1988) 170(6):2886), and taken in further view of Shah *et al.* (U.S. Patent No. 5,521,300). While Applicants submit that the Examiner has failed to make out a *prima facie* case of obviousness, they are nevertheless submitting herewith a Declaration Under 37 C.F.R. § 1.132 which provides evidence of surprisingly good amplification results achieved with oligonucleotides of the rejected claims. This Declaration details an experiment conducted before the priority date of the instant application (dates redacted) by Yeasing Yang, a co-inventor, in which the performance of a primer set made up of a primer having the base sequence of SEQ ID NO:2 (identified as "MgoA(+)"146") and a promoter-primer having a T7 promoter sequence and the base sequence of SEQ ID NO:22 (identified as "T7AMtbA(-)"246") was compared with a primer set targeting a 23S rRNA region of *M. tuberculosis* (identified as "Mtb(+)"237" and "T7AMtbB(-)"290-3'RP"). The primer sets were tested in sets of six under identical conditions and the results are presented in relative light units ("RLU"). See Declaration, Exhibit A. The results show that the primer set of the claimed invention (see samples 3-8) gave surprisingly uniform results compared to the 23S rRNA primer set (see first set of samples 1-6). As indicated in the Declaration, the 23S rRNA primer set in this experiment had been considered for development of a commercial *M. tuberculosis* assay by Gen-Probe Incorporated, the inventors' employer and the assignee of the instant application, prior to conducting the experiment detailed in Exhibit A. Based on the provided Declaration data, Applicants submit that the indicated oligonucleotides of the rejected claims should be patentable in view of their unexpectedly good properties as amplification oligonucleotides targeting a structured and unpredictable target nucleic acid. See MPEP § 716.02(a) at 700-258 (8th ed. Rev. 2, May 2004). Accordingly, withdrawal of this rejection is respectfully requested.

Sequence Listing

On May 30, 1996, Applicants filed an Amended Sequence Listing deleting nucleotide positions 41-47 ("GGGATAA") from SEQ ID NO:1 of their original Sequence Listing. Applicants wish to note for the record that this amendment to the Sequence Listing was made to properly reflect the primer portion of SEQ ID NO:1, which primer portion is identified as SEQ ID NO:22 of the

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corrected Sequence Listing filed on January 16, 1996. The sequence of SEQ ID NO:22 finds support in, for example, claim 40 of grandparent application Serial No. 07/925,405. By comparing the sequences of SEQ ID NO:1 and SEQ ID NO:22, one skilled in the art would clearly recognize that the inclusion of "GGGATAA" at nucleotide positions 41-47 of SEQ ID NO:1 in the original Sequence Listing was an error and should not have been included. *See* MPEP § 2163.07.II at 2100-183 (8th ed. Rev. 2, May 2004) ("An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction."). Accordingly, no new matter was added by Applicants' Amended Sequence Listing.

Conclusion

Applicants submit that the subject application is in condition for allowance and Notice to the effect is respectfully requested.

Please charge any fees due in connection with this Reply to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

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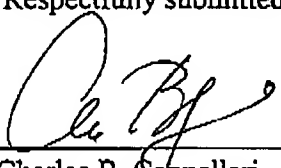
Certificate of Transmission

I hereby certify that this correspondence (and any referred to as attached) is being sent by facsimile to 703-872-9306 on the date indicated below to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Respectfully submitted,

Dated: November 16, 2004

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